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EXAMINER

BLANCHARD, DAVID J

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/029,926

Applicant(s)

HAGAY ET AL.

Examiner

David J Blanchard

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. This election/restriction requirement sets forth multiple elections applicable to the Inventions of Groups I, III-IV and VIII-IX (see item nos. 2-5 below).

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-3, 5-14, 18-19, 22-24 and 28-29, drawn to a peptide or polypeptide comprising an Fv molecule, classified in class 530, subclass 388.8.
 - II. Claim 4, drawn to a scFv molecule that has the amino acid sequence of SEQ ID NO:25, wherein the first hypervariable region (CDR) is identical to SEQ ID NO:8, classified in class 530, subclass 387.3.
 - III. Claim 15-17, drawn to a peptide or polypeptide comprising an Fv molecule that has the amino acid sequence of SEQ ID NO:61, classified in class 530, subclass 387.1.
 - IV. Claims 20, 25 and 26, drawn to a peptide or polypeptide comprising an Fv molecule wherein the CDR2 and CDR1 regions have the amino acid sequences SEQ ID NO:115 and SEQ ID NO:114, respectively, classified in class 424, subclass 130.1.
 - V. Claim 21, drawn to a peptide or polypeptide comprising an Fv molecule wherein the CDR3, CDR2 and CDR1 regions have the amino acid

sequences SEQ ID NOS:8, 115 and 114, respectively, classified in class 424, subclass 133.1.

- VI. Claim 27, drawn to a peptide or polypeptide comprising an Fv molecule wherein CDR3 is SEQ ID NO:8, CDR2 is SEQ ID NO:115, CDR1 is SEQ ID NO:114, CDR3 is flanked by SEQ ID NOS: 117 and 116, CDR2 is flanked by SEQ ID NOS:119 and 118, CDR1 is flanked by SEQ ID NOS: 121 and 120, classified in class 530, subclass 387.3.
- VII. Claim 30, drawn to a method for selecting an Fv peptide or polypeptide comprising biopanning of phage, classified in class 435, subclass 5.
- VIII. Claims 31-33, drawn to a peptide or polypeptide comprising an Fv molecule, wherein the Fv binds to a substantially exposed and/or over-expressed binding site on or in a target cell, classified in class 530, subclass 388.1.
- IX. Claims 34-36, drawn to a peptide or polypeptide comprising an Fv molecule comprising a first and second chain each comprising a first, second and third hypervariable region, classified in class 424, subclass 141.1.
- X. Claims 37-41, drawn to a peptide or polypeptide comprising an Fv molecule that binds to an unknown ligand on a cell first cell, classified in class 530, subclass 350.

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3. For each of invention sets I, III-IV, VIII-IX above, restriction to one of SEQ ID NOS:8-24 is also required under 35 U.S.C. 121. Therefore, election is required of one of Inventions I, III-IV, VIII-IX and one of SEQ ID NOS:8-24. This is not an election of species.
4. For each of invention sets I and III above, restriction to one of SEQ ID NOS:30-113 is also required under 35 U.S.C. 121. Therefore, election is required of one of Inventions I, III and one of SEQ ID NOS:8-24 and one of SEQ ID NOS:30-113. This is not an election of species.
5. For invention set IX above, restriction to one of SEQ ID NOS:1-6, 125-202 is also required under 35 U.S.C. 121. Therefore, if Invention IX is elected, election is required of one of SEQ ID NOS:8-24 and one of SEQ ID NOS: 1-6, 125-202. This is not an election of species.
6. If applicant elects the Invention of Group I, applicant is also required to elect one of the following patentably distinct species. This is a species election. This application contains claims directed to the following patentably distinct species of the claimed invention:
 - (A) carcinoma
 - (B) sarcoma
 - (C) leukemia
 - (D) adenoma
 - (E) lymphoma
 - (F) myeloma
 - (G) blastoma
 - (H) seminoma
 - I) melanoma

The species are distinct because they have different etiologies and different effects,

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claim 1 is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I-VI and VIII-X represent separate and distinct products, which are made by materially different methods, and are used in materially different methods, which have different modes of operation, different functions and different effects. The peptides or polypeptides of Groups I-VI and VIII-X are all structurally and chemically different from each other. The peptides or polypeptides of Groups I-VI and VIII-X are patentably distinct because the CDRs and frameworks are structurally distinct and require different CDR sequences and different framework sequences and thus, are structurally distinct and art on one sequence would not necessarily be art on the others. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I-VI and VIII-X are patentably distinct.

Inventions VII and (I-VI, VIII-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the peptide or polypeptide comprising an Fv molecule of Groups I-VI and VIII-X can be used as an

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immunotoxin in methods of treatment in addition to the materially different method of Group VII.

8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classifications, restriction for examination purposes as indicated is proper.

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims

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and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.


10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Blanchard whose telephone number is (571) 272-0827. The examiner can normally be reached at (571) 272-0827 from 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

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Official papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The official fax number for Group 1600 where this application or proceeding is assigned is (703) 872-9306.

Respectfully,
David J. Blanchard
571-272-0827



LARRY R. HELMS, PH.D
PRIMARY EXAMINER